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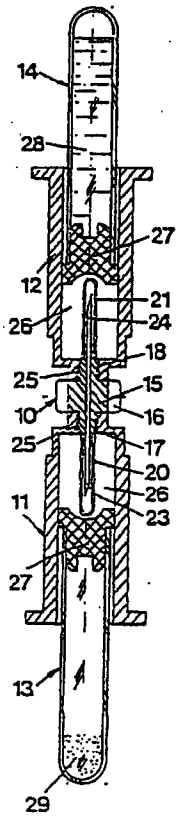
(54) Title: TRANSFER DEVICE

(57) Abstract

A device for transferring at least one substance in a closed system between at least two vessels (13, 14) and further to use. The vessels are connectable to each other via a connecting member (10) which is provided with a through cannula (22), at which the inner space of the vessel as well as the cannula, separately, are enclosed by membrane-like closures which are perforateable by the cannula. To both ends of the connecting member (10), coaxially with the cannula, there is connected a sleeve-shaped holder (11, 12) each for said vessel. The cannula is provided with a point in both ends, which points extend into a holder (11, 12) each. The connecting member (10) has in both end portions coupling means (17, 18) for disconnectable coupling to the holders (11, 12), and membrane-like enclosures are attached to said end portions, for example formed like protective sheaths (20, 21) or the like, which surrounds the free end portions (23, 24) of the cannula.



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TRANSFER DEVICE

The present invention relates to a device for transferring at least one substance in a closed system between at least two vessels and further to intended use, and which vessels are connectable to each other via a connecting member which is provided with a through cannula, at which each of the inner spaces of the vessels as well as the cannula, separately are enclosed by a membrane-like closure which is perforateable by the cannula, and to both ends of the connecting device, coaxially with the cannula, there is connected a sleeve-shaped holder each for said vessel, and said cannula is provided with a point at both ends and which points extend into a holder each.

Background of the invention

The use of drugs, nutrition solutions and the like which consist of several components, for example a freeze-dried substance which must be dissolved in a liquid before use and which components in solution has a very short lifetime and therefore must be kept aparted from each other is more and more common. One example of such substances is cytostatica of different kinds, compositions which contain isotopes or allergy inducing substances and which must be handled in such a way that the staff cannot be contaminated by them, neither by breathing nor touching or in another way.

A transfer device is known from the Norwegian patent 141.537, which comprises a double-pointed cannula, one end of which is protected by an elastic protective sheath. The transfer device is provided with a piston-like flange, intended to cooperate with a resilient stopper in an ampoule which can be inserted into this. The opposite end of the cannula is intended to be passed through the membrane into a bottle which contains for example an infusion solution, and to which bottle the content of the ampoule is transferred when the flange of the transfer

device is pressed into the ampoule. This device can be used only if the substances in both vessels are liquid. But it is not possible to use the system to dissolve a solid substance. Further, it is not possible to use this known device to inject the drug to the patient without risks for contamination.

A blood-sampling device with a non-return valve cannula is also known, which consists of a double-pointed cannula which is sharpened like a lancet in both ends, one end of which is made for vein punction while the other end is protected by an elastic protective sheath. The cannula is fixed to a connecting member which is provided with taps and which device can be screwed on a sleeve-shaped holder. In this holder a vacuum tube which is sealed by a rubber stopper is insertable, so that the rear end of the cannula pierces the rubber stopper. The device is used for blood-sampling, at which the negative pressure in the vacuum tube will provide the desired suction effect. When the vacuum tube is taken out from the holder, the elastic protective sheath will enclose the end portion of the cannula again.

A transfer device in a closed system is known from the Swedish patent 8301176-7, in which all parts which are active during the transfer, i.e. the cannula, all the vessels which are used and also the part which is connected to the patient, are sealed by a membrane each which is penetrateable by the cannula, so that each part, also when taken apart, is encapsulated so that contamination is impossible. This known device has turned out to bo very reliable and efficient, but it is relatively complicated with regard to construction as well as to manufacture and to use.

Object and features of the invention

The object of present invention is to provide an absolutely safe transfer device between different vessels and the patient, which device is simple and cheap to produce and which partially uses techniques which are well known in the medical care. This has been solved by that the connecting member at

both end portions is provided with coupling means for disconnectable coupling to the respective holder, and membrane-like enclosures are attached to said end portions, for example shaped like protective sheaths or the like, which surround the free end portions of the cannula.

Description of the drawings

The invention will below be closer described with reference to some embodiments.

Figure 1 shows a section through a transfer device according to the invention in cooperation with a vacuum tube.
Figure 2 shows the transfer device according to figure 1, in which one of the vessels is replaced by a cylinder-piston device.
Figure 3 shows a section through a transfer device which is ready for injection or other transfer.
Figure 4 shows a section through a holder with transfer means for alternative connection to a vein-catheter, a cannula or a protective sleeve.
Figure 5 shows the connecting device in a side view partially in section.
Figure 6 shows a section through a transfer device according to the invention with a holder for connection to a bottle.
Figure 7 shows a section on an enlarged scale through the upper part of a vessel which can be used as a cylinder-piston device.
Figure 8 is a section along the line VIII-VIII in figure 7.
Figure 9 shows a section through a transfer device according to the invention, where the vessel shown in figure 7 is used.

Description of embodiments

The transfer device according to the invention consists of a central connecting member 10, at least two sleeve-shaped holders 11 and 12 which are connectable to the transfer member, and to several vessels which can be inserted into these holders, at which figure 1 shows the vessels 13 and 14.

The connecting member 10 comprises a central body 15 with finger grip grooves 16 and two axial taps 17 and 18 arranged opposite to each other, which in both end portions are formed with a connecting nipple 19 each for an elastic protective sheath 20, 21. Each protecting sheath encloses a cannula 22 which extends through the central body to which it is fixed, the free end parts 23, 24 of the cannula are positioned in an elastic protective sheath each. The protective sheaths are fixed to a nipple each. To each one of the taps 17, 18 of the transfer device 10 a holder 11,12 is screwable, which are provided with threaded holes 25 corresponding to the taps 17,18. The nipples 19 and the protective sheaths 20,21 which are attached to them, are dimensioned so that they can be passed through the threaded holes 25 of the holders, so that the end parts 23,24 of the cannula 22 extends axially into the respective holder 11,12.

Vessels 13,14 are insertable in each of the inner spaces 26 of the sleeve-shaped holders 11,12, which vessels in the embodiment of figure 1 comprise a vacuum tube 13, i.e. a glass tube which is sealed in one end and the opening is closed by a rubber seal in the form of a rubber stopper 27, and a similar sealed vessel 14, for example an ampoule which is filled with a liquid 28 intended as a solvent for the dry substance 29 in the vacuum tube 13.

The transfer of the liquid 28 from the ampoule 14 to the vacuum tube 13 is provided by inserting the ampoule with its sealing 27 into the inner space 26 of the holder 12 so that the rubber stopper 27 as well as the elastic protective sheath is perforated by the free end part 24 of the cannula. As the elastic protective sheath 20 at the opposite end 23 of the cannula 22 forms a closed space, no liquid will be transferred thereto. The transfer of the liquid 28 to the vacuum tube 13 is provided by inserting this into the inner space 26 of the holder 11, so that the rubber stopper 27 and the elastic protective sheath 20 are penetrated by the end part 23 of the cannula. The liquid is by the vacuum sucked out from the ampoule 14 to the vacuum tube 13 where the liquid dissolves

the dry substance 29. The ampoule may consist of a flexible material, so that it can be compressed when the liquid 28 is transferred to the vacuum tube 28. Alternatively, the liquid is enclosed in a bag arranged inside the ampoule. The ampoule 14 can thereafter be removed from the holder 12, at which the protective sheath 21 resumes its protecting position over the end part 24 of the cannula.

Thereafter, a vessel 30 is inserted to the holder 12, said vessel comprising a cylinder 31, a piston 32 with a piston rod 33 which is displaceable within the cylinder, and a sealing 34 in the form of a rubber stopper, which can be inserted in one of the open ends of the cylinder. In the same way as in the vessels 13, 14, the vessel 30 can be connected to the cannula point 24 of the connecting member 10, by the fact that this perforates the rubber stopper 34. The mixture of solvent 28 and substance 29 in the vessel 13 can now be transferred to the vessel 30 by bringing the piston 32 backwards a distance corresponding to the volume which is to be injected to the patient or be used for some other purpose. Thereafter, the vessel 13 can be displaced from the holder 11, at which the elastic covering sheath 20 resumes its protecting position around the end part 23 of the cannula 22. Thereafter, if desired, the holder 11 can be unscrewed from the connecting member 10, as shown in figure 3. Now, the mixed drug is ready to be injected by means of the vessel 30 which is formed like a syringe or be transferred in another way for further use.

The cannula 22 of the connecting member 10 can be designed so that it can be used directly as a cannula for injection to a patient, but if alternative possibilities for connection are desired, for example if very thin cannulas are to be used or if the injection is to be performed through a vein cateter, a connecting member 10 is used in which one tap has been replaced by a so called luer coupling 36, to which a cannula 34, a catheter 35 or a protective sleeve 37 can be connected in a conventional way as is shown in figure 4.

Depending on the shape of the ampoule 14 and 38 (fig. 6) a

corresponding holder 12 is used. The holder 12 according to figure 6 is shaped so that a conventional bottle-like ampoule can be inserted in the holder with its sealed end, at which the bottle sealing comprises a rubber stopper 39, which is perforateable by one of the cannula points 24 of the connecting member 10, after it has pierced the elastic covering sheath 21. The ampoule 38 can either contain the liquid which can be used as solvent and which in this case is sucked by means of the vessel 30 which is formed like a syringe, after which a vacuum tube 13 is connected to the holder 11 which contains the substance 29 which will be dissolved by the solvent. Another possibility is to use the bottle 38 as a vacuum container in which the substance which will be dissolved is placed.

Another possibility to handle such substances is shown in the embodiment in fig. 7-9, wherein the sealing 40 also makes a container for the substance. For this purpose, the sealing 40 which is formed as a rubber stopper is provided with a flexible vessel 41, for example formed as a folded expandable "bag", which makes a unit with the rubber stopper. The bag and the rubber stopper can be made in one piece of the same material, but it is also possible to make the bag of a transparent, flexible material so that the contents of the container can be seen from the outside. The rubber stopper 40 with the adhering bag 29, which by the pharmaceutial industry is delivered with the substance enclosed, is applied in the opening of the vessel 30 which is formed as a syringe, instead of the rubber stopper 34. As shown in figure 9, the solvent is added to the flexible bag 41 by a second vessel 30b which is provided with a piston and a cylinder, by which vessel a solvent is transfered via the connecting member 10 to the flexible bag 41. In oroer to be able to recieve and emit liquid from the flexible bag 41, the inner space 42 of the vessel 31a, i.e. the space between the bag and the cylinder wall 31a, communicates with the outer athmosphere via venting passages 43 which are arranged in the rubber stopper 40 and/or via corresponding passages 44 in the piston 32a. The flexible bag 41 can expand as far as the piston 32a admits and by means

of the last mentioned the content of the bag can also be under pressure, if the substance in the bag is to be injected or in another way be transferred to further use.

By storing the substance 29 which is to be dissolved by a liquid either in a vacuum vessel 13,38 or in a sealed flexible bag 41 which is treatable from the outside, it is possible to avoid special pressure compensating devices, for example balloons, which else are required when using closed systems. Since through cannulas with points in its both ends as well as the use of rubber stoppers for sealing of sampling tubes, for example when sampling blood tests, are well known in the medical care the use of this kind of devices is well known, and therefore this new developed technique should not cause any difficulties.

The invention is not limited to the shown embodiments, but several variations are possible in the scope of the claims. Of course, it is possible to combine the different parts of the different embodiments with each other if desired. It is also possible to design one or some of the vessels of the system with a flexible wall which can be manually compressed if the content of the vessel is to be pressed out through a cannula which is inserted through the sealing.

CLAIMS

1. A device for transferring at least one substance between at least two vessels (13,14,30,38) in a closed system and further to the intended use, and which vessels are connectable to each other via a connecting member (10) which is provided with a through cannula (22), at which the inner space of the vessel as well as the cannula, separately, are enclosed by a membrane-like closure (20,21,27,34,39,40) which is perforateable by the cannula, and to both ends of the connecting member (10), coaxially with the cannula (22) there is connected a sleeve-shaped holder (11,12) each for said vessel, and the cannula (22) is provided with a point at both ends and which points extends into a holder each,
c h a r a c t e r i z e d b y,
that the connecting member (10) at both end portions is provided with coupling means (17,18) for disconnectable coupling to the respective holders (11,12), and membrane-like closures are attached to said end portions, for example shaped like protective sheaths (20,21) or the like, which surround the free end portions (23,24) of the cannula.

2. A device according to claim 1,
c h a r a c t e r i z e d b y,
that the said coupling means (17,18) consist of taps which are arranged coaxially with the cannula (22).

3. A device according to claim 1 or 2,
c h a r a c t e r i z e d b y,
that at least one of the vessels (30) on the side remote from the membrane-like closure (34,40) is cylinder- shaped and provided with a piston (32) displaceable in the cylinder.

4. A device according to claim 3,
c h a r a c t e r i z e d b y,
that inside the cylinder (31), between the closure (40) and the piston (32), there is arranged an inner flexible vessel

(41) which is actuatable by the piston.

5. A device according to claim 4, characterized by, that the flexible vessel (41) and the closure (40) are made to form an unit, in which one of said substances (29) is positioned.

6. A device according to claim 4, characterized by, that the inner space (42) of the cylinder (31) which is positioned outside the flexible vessel (41) is arranged to communicate with the atmosphere.

7. A device according to claim 6, characterized by, that in the closure (40) of the cylinder (31) and/or in the piston (32) there is arranged at least one passage (43,44).

8. A device according to claim 1 or 2, characterized by, that at least one of the vessels consists of a flexible tube which is closed in the end which is remote from the closure.

FIG 1

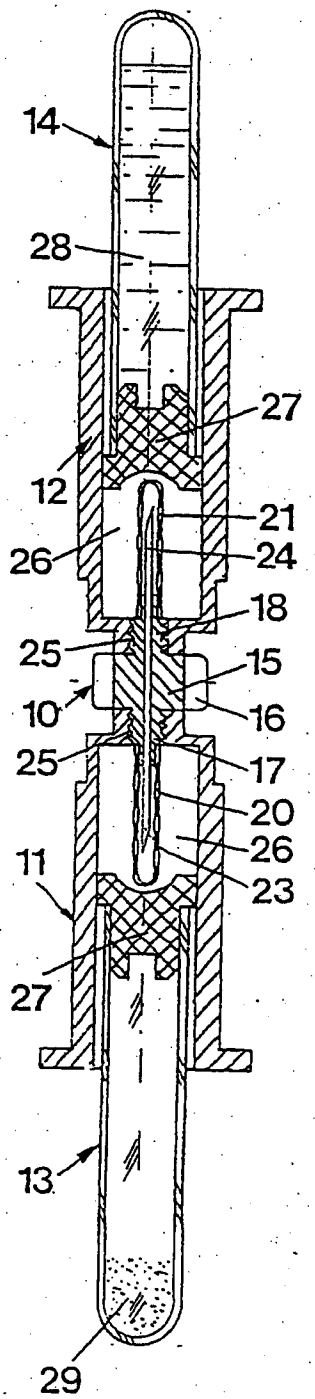


FIG 2

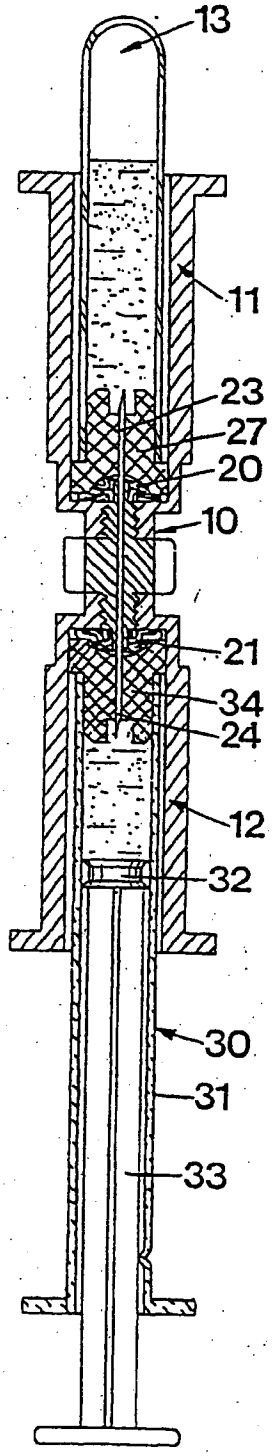


FIG 3

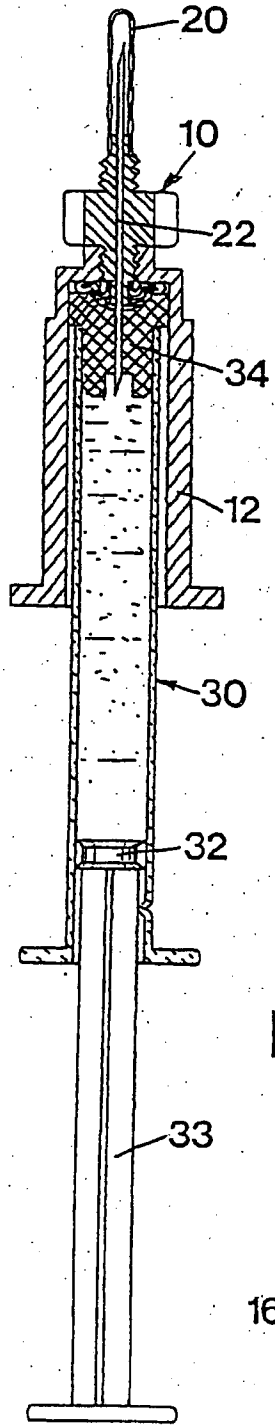


FIG 4

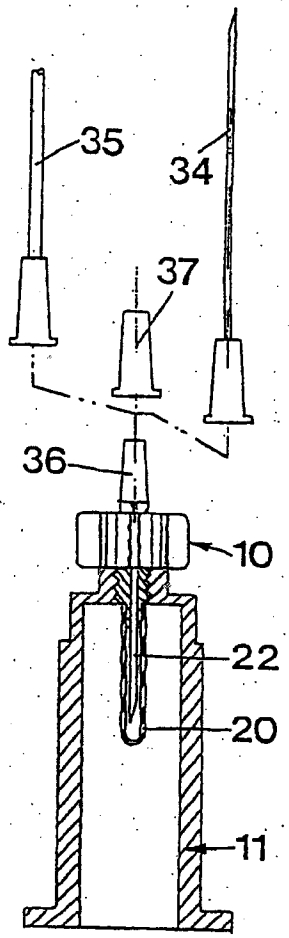


FIG 5

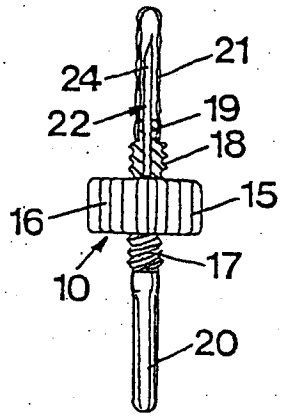


FIG 9

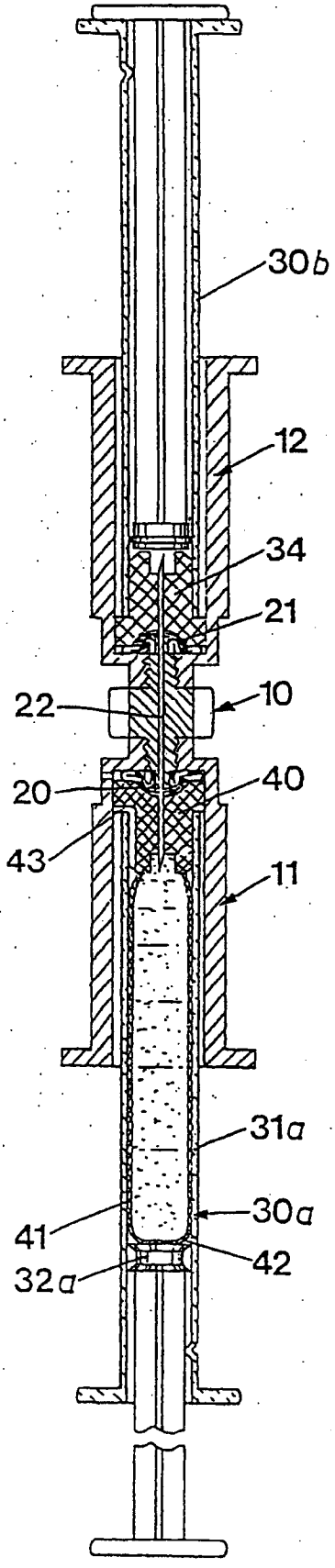


FIG 6

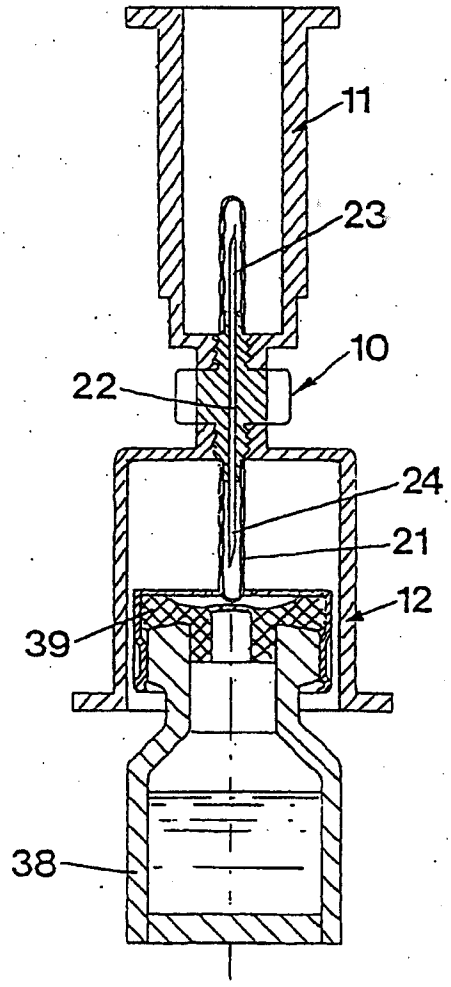


FIG 7

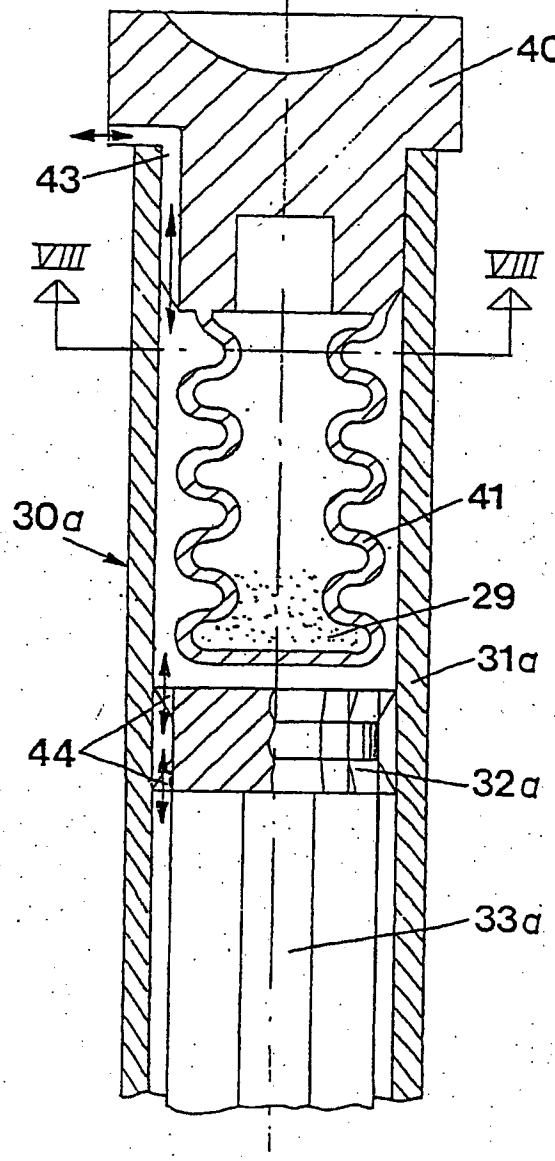
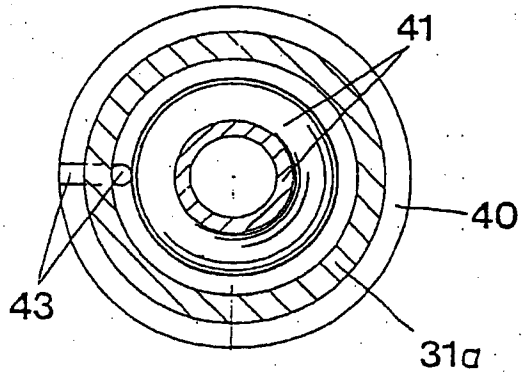


FIG 8



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE86/00149

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 J 1/00, A 61 M 5/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC 4	A 61 J 1/00, /06; A 61 M 5/00, /18, /31, /32, /34; B 65 D 81/32
US Cl	128: 218R, 218M, 247, 272, 272.1, 272.3; .../...

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	FR, A1, 2 293 916 (BOISNARD J-Y, MARTIAL L) 9 July 1976	1
Y	DE, A, 1 766 152 (FARBENFABRIKEN BAYER AG) 3 June 1971 & NL, 6905156 FR, 2006010 BE, 731349	1-3
Y	DE, A, 2 157 582 (FARBWERKE HOECHST AG) 30 May 1973 & NL, 7215451 FR, 2160668 BE, 791634 LU, 66493 CH, 556171 GB, 1419061 AT, 350709	1-3
X	DE, A, 1 566 628 (LAPIS ENGINEERING COMPANY LTD) 30 April 1970 & FR, 1555711	3-5

.../...

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1986-06-18	1986 -06- 24
International Searching Authority	**Signature of Authorized Officer**
Swedish Patent Office	Folke Svensson

MJ

Form PCT/ISA/210 (second sheet) (January 1985)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

II Fields Searched (cont)

141: 329;

604: 82, 87-92, 403, 411-416

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ..... because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically:

3. ☐ Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the International application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
X	US, A, 3 166 070 (S J EVERETT) 19 January 1965	4,6-7
X	FR, A, 1 103 541 (STEINER) 3 November 1955 see figure 3	8
A	FR, A1, 2 473 017 (SIGMA - TAU INDUSTRIE FARMACEUTICHE RIUNITE SpA). 10 July 1981	
A	US, A, 1 718 593 (A E SMITH) 25 June 1929	
A	US, A, 3 872 867 (KILLINGER) 25 March 1975	